



U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

Certificate No. 10149-6-2022

CERTIFICATE TO FOREIGN GOVERNMENT

In order to allow the importation of United States products into foreign countries, the U.S. Food and Drug Administration (FDA) certifies the following information concerning the product(s) to be exported listed below:

Name of Product(s)

See Attached List

(Two Pages)

Name of Manufacturer/Distributor, Address

Name of Manufacturer

Manufacturer

SUNTECH MEDICAL, INC.
5827 S. Miami Boulevard Suite 100
MORRISVILLE, NC USA 27560

The product(s) described above (and the manufacturing/distribution site(s) which produces/distributes it) is subject to the jurisdiction of the FDA under the Federal Food, Drug, and Cosmetic Act.

It is certified that the above product(s) may be marketed in, and legally exported from, the United States of America at this time. The manufacturing plant(s) in which the product(s) is produced is subject to periodic inspections. The last such inspection showed that the plant(s), at that time, appeared to be in substantial compliance with current good manufacturing practice requirements for the product(s) listed above.

Sincerely,

CDR Cesar A. Perez, PhD, Director
DRP2: Division of Establishment Support
Office of Regulatory Programs
Office of Product Evaluation and Quality
Center for Devices and Radiological Health
U.S. Food and Drug Administration, DHHS

This certificate is valid from June 24, 2022 to June 23, 2024.





**U.S. FOOD & DRUG
ADMINISTRATION**

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

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Certificate to Foreign Government - Name of Product(s) Attachment Page 1 of 2

Name of Manufacturer

Manufacturer

SUNTECH MEDICAL, INC.
5827 S. Miami Boulevard
Suite 100
MORRISVILLE, NC
USA 27560

Name of Product(s)

SunTech Ambulatory Blood Pressure Monitors, Model 250 & 250D
99-0133-00, System, Oscar 2, Model 250, Standard
99-0133-01, System, Oscar 2, Model 250, Standard, Bluetooth
99-0133-02, System, Oscar 2, Model 250, Central BP
99-0133-03, System, Oscar 2, Model 250, Central BP, Bluetooth
99-0133-04, System, Oscar 2, Model 250, Standard China
99-0133-05, System, Oscar 2, Model 250, Standard, Bluetooth
99-0133-06, System, Oscar 2, Model 250, Central BP China
99-0133-07, System, Oscar 2, Model 250, Central BP, Bluetooth
99-0133-14, Oscar 2 ABP Monitor Without Batteries - Standard
99-0133-15, Oscar 2 ABP Monitor Without Batteries - Bluetooth
99-0133-16, Oscar 2 ABP Monitor Without Batteries - w/ SphygmoCor Inside
99-0133-17, Oscar 2 ABP Monitor Without Batteries - w/ SphygmoCor Inside - Bluetooth
99-0233-00, System, M250D ABPM Bravo Mini, Standard, 1 Button
99-0233-01, System, M250D ABPM, Standard, 3 Button
99-0233-10, System, M250D ABPM, Standard 3-Button
99-0233-20, System, M250D ABPM, Standard 1-Button
99-0233-30, System, M250D ABPM, Standard, 1 Button
99-0233-50, System, M250D ABPM, Standard 3-Button
99-0233-60, System, M250D ABPM, Standard, 1 Button
NJ124, System, M250D ABPM, Standard 1-Button
98-0239-01 ABPM Cuff, Size 1
98-0239-02 ABPM Cuff, Size 2
98-0239-03 ABPM Cuff, Size 3
98-0239-04 ABPM Cuff, Size 4
98-0239-21, ABPM Cuff, Size 1, With Bayonet(Plastic) Connector
98-0239-22, ABPM Cuff, Size 2, With Bayonet(Plastic) Connector
98-0239-23, ABPM Cuff, Size 3, With Bayonet(Plastic) Connector
98-0239-24, ABPM Cuff, Size 4, With Bayonet(Plastic) Connector
98-0239-31, ABPM Cuff, Size 1
98-0239-32, ABPM Cuff, Size 2
98-0239-33, ABPM Cuff, Size 3
98-0239-34, ABPM Cuff, Size 4
NJ118, Agilis Mini Orbit Cuff, Size 1
NJ119, Agilis Mini Orbit Cuff, Size 2
NJ120, Agilis Mini Orbit Cuff, Size 3
NJ121, Agilis Mini Orbit Cuff, Size 4
98-0239-51, ABPM Cuff, Size 1
98-0239-52, ABPM Cuff, Size 2
98-0239-53, ABPM Cuff, Size 3
98-0239-54, ABPM Cuff, Size 4
98-0239-61, ABPM Cuff, Size 1
98-0239-62, ABPM Cuff, Size 2
98-0239-63, ABPM Cuff, Size 3
98-0239-64, ABPM Cuff, Size 4
98-0600-01 OPD Child Cuff
98-0600-41, Cuff, SunTech Durable One-Piece Cuff, Child, 1-Tube, Bayonet, Box of 5
NJ108, M250D Pouch, Neoprene
98-1020-00, M250D Pouch, Neoprene





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98-1020-01, M250D Pouch Neoprene
98-1020-02, M250D Pouch Neoprene
98-1020-04, M250D Pouch Neoprene
98-1020-05, M250D Pouch Neoprene
98-0036-00, Strap, Shoulder, Standard, Labeled
NJ009, Strap, Shoulder Strap ABP
98-0036-03, Strap, Shoulder, ABPM
98-0036-04, Strap, Shoulder, ABPM
98-0036-05, Strap, Shoulder, ABPM
98-0037-00, Belt, ABPM
NJ012, Belt, ABPM
98-0037-02, Belt, ABP, Standard
98-0037-03, Belt, M250D
98-0037-04, Belt, M250D
98-0037-05, Belt, M250D
98-0032-07 Pouch, Oscar 2, Model 250, Labeled
98-0032-00 Pouch, Oscar 2, 222, Neoprene, Labeled
97-0090-02 USB/Serial Oscar Cable
NJ123, USB-A TO USB-C 3 FT INTERFACE
91-0143-02, USB-A to USB-C, 3 FT Interface Cable
91-0143-00, Interface Cable, USB/C to USB/A, 3 Ft
91-0130-00, Cable, USB, Micro USB, Oscar 2, Model 250' Labeled
NJ127, Patient Hose, Bayonet to Bayonet
91-0032-79, Patient Hose, Black, 4 Foot, Female Rectus to Female Rectus Connector
91-0032-80, Patient Hose, 4 FT Female Rectus
91-0032-82, PATIENT HOSE, 4 FEET, FEMALE TO FEMALE BAYONET.
91-0032-83, PATIENT HOSE, 4 FEET, FEMALE TO FEMALE BAYONET
45-0004-00, SunTech Oscar 2 Carrying Case
NJ100, Software and Documents USB Drive, Model 250D, Agilis Mini
27-0185-A1, USB Flash Drive, AWP4
27-0145-A1, AWP4 USB Flash Drive
27-0144-A1, USB Flash Drive, AccuWin Pro v4

-----END OF PRODUCT LIST-----

